

### **REMARKS**

After entry of this amendment, claims 45, 47-61 and 63 are pending. Claim 62 has been cancelled without prejudice or disclaimer. New claim 63 has been added and finds support *inter alia* in the original claims. Further support for new claim 63 is found in the specification at page 14, lines 10-11. The new claim is re-written independent form from cancelled claim 62, and further narrows the scope of claim 1 by adding additional limitations and thus, do not present any new issues that require further consideration or search. Additionally, the total number of claims is not increased in view of the cancellation of claim 62. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. No new matter has been added. Applicants respectfully request entry of the above claim amendment as they are believed to put the claims in condition for allowance or, alternatively, in better form for consideration on appeal. Thus, entry under 37 CFR §1.116 is correct.

### **Claim Rejections – 35 U.S.C. § 112**

Claims 61 and 62 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, and under 35 U.S.C. § 112, second paragraph, as failing to comply with the written description requirement for containing “new matter.” In light of the present amendment, withdrawal of the rejections is respectfully requested.

### **Claim Rejections – 35 U.S.C. § 103(a)**

Claims 45 and 47-62 stand rejected under 35 U.S.C. § 103(a) as being obvious over Harper *et al.* (hereinafter “Harper”), in view of Sowa *et al.* (hereinafter “Sowa”), and further in view of Nykiforuk. Applicants respectfully disagree and urge reconsideration of the rejection for the following reasons.

The Examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994). It is further noted that the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), indicated that the *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), factors

still control an obviousness inquiry. Among other things, the “scope and content of the prior art” and the “differences between the prior art and the claims” must be considered. Moreover, it is the invention as a whole, and not some part of it, which must be obvious under 35 U.S.C. §103. *In re Antonie*, 559 F.2d 618, 619 (CCPA 1977). Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.3d 1531.

Furthermore, it is well established that under 35 U.S.C. § 103 the Examiner must consider the reference as a whole. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). In addition, the Examiner cannot selectively pick and choose from the disclosed parameters without proper motivation as to a particular selection. The mere fact that a reference may be modified to reflect features of the claimed invention does not make the modification, and hence the claimed invention, obvious unless the prior art suggested the desirability of such modification. *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430 (Fed. Cir. 1990); *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992). “[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art . . . it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does.*” See *KSR International Co. v. Teleflex Inc.*, 1741 82 USPQ2d 1385, 1396 (2007) (emphasis added). As noted by the court in *In re Kubin*, 2009 U.S. App. LEXIS 6914 (Fed. Cir. 2009), one impermissible “obvious to try” situation that is erroneously equated with obviousness under § 103 is where one skilled in the art would have to vary all parameters or try each of numerous possible choices to possibly arrive at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. Similarly, it is impermissible to simply engage in a hindsight reconstruction of the claimed invention where the reference itself provides no teaching as to why the applicant’s combination would have been obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

The Examiner relies on three references, (1) Harper, (2) Sowa, and (3) Nykiforuk, to support the finding of obviousness.

Harper discloses clusters of genes that are regulated in response to a stress condition in

plants, among which hemoglobin-coding genes are included. Harper further teaches production of transgenic plants expressing the disclosed stress-regulated genes. See e.g., claim 29. According to the teaching of Harper, the transgenic plants would exhibit altered responsiveness to a stress condition. However, Harper does not teach or suggest any other advantage or usefulness that might be resulted from overexpressing any of the disclosed genes, including the hemoglobin-coding genes. There is no suggestion of increasing the starch and/or oil content in transgenic plants.

Sowa teaches that the hemoglobin potentially functions in plants as to maintain the energy status of cells exposed to low oxygen environments. See Abstract at p. 10317. Specifically, Sowa suggests that hemoglobin maintains energy status of the cell by facilitating glycolysis to generate ATP through substrate-level phosphorylation. See page 10320, left Col., end of the first paragraph. Nowhere in the reference is the effect of overexpressing hemoglobin in increasing the starch and/or oil content in a plant taught, discussed, or even suggested.

Nykiforuk teaches diacylglycerol O-acyltransferase (DGAT) coding genes and their use in transgenic plants for increasing triacylglycerol (TAG) synthesis, seed oil content, and oil quality in plants. See Nykiforuk, Abstract. The Examiner relies on Nykiforuk for teaching a method of recovering oil from a transgenic plant, but this reference suggests nothing about hemoglobin genes.

It is thus apparent that the “differences between the prior art and the claims” primarily is the use of overexpressing hemoglobin to increase the starch and/or oil content in a plant and the use of such hemoglobin transformed plants in producing starch and/or oil. Harper and Sowa, alone or in combination, do not teach or suggest any correlation between overexpressing hemoglobin in a transgenic plant and the content of starch and/or oil in such a transgenic plant. Absent such a teaching, one skilled in the art would not have had motivation to make the presently claimed invention, nor a reasonable expectation that the content of starch and/or oil in a hemoglobin-transformed plant would be increased.

The Examiner contends that, because Harper teaches the overexpression of at least one hemoglobin in a plant, it would naturally follow that starch and/or oil would be increased in such a plant. Office Action at page 4. Assuming *arguendo* that such a contention is true, however, if

one skilled in the art does not realize and/or appreciate the increased content of starch and/or oil in the hemoglobin-transformed plant taught in Harper, there would be no motivation to recover the oil as recited in claim 1. Obviousness cannot be predicated on what is not known at the time an invention is made. *In re Rijckaert*, 9 F.2d 1531. The present invention is not merely recognizing additional advantage that would flow naturally from what is taught in Harper. Rather, the claimed method takes a step further after recognizing the advantageous effect of overexpressing hemoglobin in plants, which was not taught in the prior art, by using such hemoglobin-transformed plants in a method for production of starch and/or oil.

The Examiner relies on Sowa for the motivation and expectation required in supporting the finding of obviousness. Interpreting the suggested role of hemoglobin as responsible for increasing substrate phosphorylation (citing Sowa at page 10320) and alleging that the production of starch is previously known to rely upon substrate phosphorylation, the Examiner contends that it would be reasonable to expect that an increase in phosphorylation would result in an increase in processes utilizing such phosphorylation, such as starch production. Applicants respectfully disagree. It is noted initially that no evidence is cited to support the Examiner's assertion that the production of starch is known to rely upon substrate phosphorylation. Assuming *arguendo* that such an assertion is true, it is nonetheless doubtful that any and all substrate phosphorylation results in a starch increase. Moreover, when considered as a whole, Sowa merely teaches or suggests that hemoglobin maintains energy status of the cell by facilitating glycolysis to generate ATP through substrate-level phosphorylation. Nowhere in Sowa teaches or suggests any potential involvement of hemoglobin in the production of starch and/or oil, let alone the effect of overexpressing hemoglobin in increasing the starch and/or oil content of transformed plants. Accordingly, Applicants respectfully submit that Sowa does not provide the motivation and expectation required for establishing *prima facie* obviousness.

In sum, as discussed above, Harper teaches or suggests hemoglobin genes are regulated in response to a stress condition in plants and expressing hemoglobin genes in transgenic plants may alter plants' responsiveness to the stress condition. Sowa teaches or suggests that hemoglobin may play a role in maintaining the energy status of cells exposed to low oxygen environments. It is thus clear that, Harper and Sowa, alone or in combination, do not teach or suggest the correlation between hemoglobin and the production of starch and/or oil in plants.

Without such a correlation, one skilled in the art would not expect that a transgenic plant overexpressing hemoglobin would have increased starch and/or oil content. Since the expectation is lacking, it would necessarily follow that one skilled in the art would not be motivated to use such a transgenic plant for starch and/or oil production and to combine with the oil recovering procedure taught in Nykiforuk to arrive to the claimed method. Nothing in the prior art, absent hindsight, would suggest otherwise. This is exactly the impermissible "obvious to try" situation noted by the court in *In re Kubin*.

Separate consideration to claim 63 is respectfully requested. New claim 63 limits the claimed method in producing oil by growing a transformed plant that overexpresses at least one hemoglobin in a seed specific manner, wherein the expression of the at least one hemoglobin results in an increase in oil content in the seeds of the transformed plant. Assuming *arguendo* that an increase in phosphorylation would result in an increase in processes utilizing such phosphorylation, including starch production, as alleged by the Examiner, it is respectfully submitted that Sowa is no longer applicable in sustain the rejection as applied to claim 63.

For at least the above reasons, Applicants submit that the finding of obviousness can only result from the hindsight afforded by reading the present disclosure, and cannot be properly based on a fair reading of the prior art alone. Reconsideration and withdrawal of the rejection is respectfully requested.

### CONCLUSION

In view of the present amendment and further in view of the above remarks, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications, if necessary.

Applicants are submitting their response within the three-month response period. No fee is believed due. However, if any fee is due, the Director is hereby authorized to charge our Deposit Account No. 03-2775, under Order No. 13311-00008-US from which the undersigned is authorized to draw.

Respectfully submitted,

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